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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,356	05/24/2001	Olga Bandman	PF-0501-1 DIV	6186

27904 7590 07/14/2003

INCYTE CORPORATION (formerly known as Incyte
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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,356

Applicant(s)

Bandman et al.

Examiner

Patrick J. Nolan

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 14-29, 46, and 47 is/are pending in the application.
- 4a) Of the above, claim(s) 14-16, 19-29, and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 17 is/are rejected.
- 7) ☒ Claim(s) 2, 18, and 46 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Part III DETAILED ACTION

1. Claims 1-2, 14-29 and 46-47 are pending.

Applicant's election with traverse of Group I, claims 1-2, 17-18 and 46 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the methods of making the product and using the product could be searched together. This is not found persuasive because for reasons set forth in Paper No. 4. However, it is noted In re Ochiai and In re Brouwer rejoinder rules will be timely considered.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 14-16, 19-29 and 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

2. Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of a polypeptide that is 90% identical to SEQ ID NO. 1. The claims are drawn to a genus of polypeptides that are not sufficiently described. Applicant has predicted one polypeptide sequence. The specification fails to describe these genus polypeptide sequences. The full scope in Applicant's invention encompasses making any one of 20 changes to any one of 33 amino acids (20 known amino acids and 90% identity would allow one to change any one of upto 33 amino acids in a 335 amino acid protein). 33²⁰ changes leads the full scope of Applicant claimed invention to be upto polypeptides. Does Applicant contend that the written description of one sequence describes a genus of 2345734188103679287078463273601 polypeptides, just because they have claimed the sequence? The Examiner disagrees. In addition the term "biologically active fragment or immunologically active fragment" would include an essentially unlimited number of undefined compounds. In The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) the Court recognized that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus.

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See the Written description guidelines from the Federal Register Vol. 66, No. 4, Friday January 5, 2001

For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 USC 112 1st paragraph.

4. Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no written support for the term naturally in the specification or claims as originally filed. Applicant is claiming a subgenus, when the have written support for the genus, and a single species within it. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon

which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

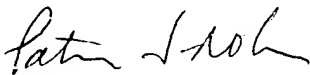
5. Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of SEQ ID NO. 1, does not reasonably provide enablement for the use of any protein that is 90% identical to SEQ ID NO. 1 or any biological fragment of SEQ ID NO. 1 or immunological fragment of SEQ ID NO. 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Claims 1 and 17 recite a protein that is 90% identical to SEQ ID NO .1, however, the present specification fails to disclose any protein which has ETS activity. In addition, the specification provides no guidance as to which of the 335 amino acids may be changed while protein activity is retained. The total number of polypeptides encompassed by the claims is 2345734188103679287078463273601 polypeptides. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain ETS activity, and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al., (U), newly cited, in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.), it would require an undue amount of experimentation for one of skill in the art to arrive at the other 2345734188103679287078463273601 polypeptides or fragments thereof, that have ETS activity.

6. Applicant is notified that claims 2, 18 and 46 are objected to as being dependent upon rejected claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 9:00 am to 5:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401.


Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
July 14, 2003